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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,907	06/30/2000	RUDI WILFRIED JAN PAUWELS	07619.0006	4853
27777	7590	03/24/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			BAKER, MAURIE GARCIA	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/530,907

Applicant(s)

PAUWELS ET AL.

Examiner

Maurie G. Baker

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-36 and 38-62 is/are pending in the application.
- 4a) Of the above claim(s) 8, 11-16, 20-23, 38-40 and 42-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 10, 17-19, 24-36 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>122203</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Response filed December 22, 2003 is acknowledged. No claims were amended, cancelled or added. Therefore, claims 1-36 and 38-62 are pending.
2. Currently, claims 42-62 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions. Also, claims 8, 11, 12-16, 20-22, 23 and 38-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species, there being no allowable generic claim.
3. Thus, claims 1-7, 9, 10, 17-19, 24-36 and 41 are currently under examination to the extent of the elected species.
4. To clarify the record with respect to the Virtanen (US 6,342,349) reference that was mentioned in the last action (referred to by applicant on page 2, 1st paragraph), this reference's teachings are described in the Restriction Requirement (paragraph 9). Since the reference does not deal with the elected species of film or tape, the reference is not currently being used in a rejection. However the teachings are indeed relevant in general and may become important in further prosecution of the instant case (e.g. if the elected species is cancelled).

Status of Rejections

5. The previous rejection under 35 U.S.C. 112, first paragraph for lack of written description is withdrawn from claims 1, 29 and 30 and maintained over claim 31. The rejections under 35 U.S.C. 112, second paragraph are maintained as well. Applicant's arguments are addressed following each maintained rejection. Note that the previous rejection over Schwabacher et al (US 2002/0006604) is withdrawn in view of applicant's arguments. However, new art rejection(s) are set forth in this action. Thus, this action remains in non-final status in view of the new rejection.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. Applicant's claims are directed to a method for the rapid screening of analytes. Claim 31 refers to a "so-called

intelligent material”. The disclosure simply does not adequately describe the “so-called intelligent material”. Applicant’s claimed scope represents only an invitation to experiment.

The language of the specification should describe the claimed invention so that one skilled in the art can recognize what is claimed. A description of a compound in terms of its function fails to distinguish the compound from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175).

The disclosure is neither representative of the claimed genus, nor does it represent a substantial portion of the claimed genus. Moreover the claimed genus encompasses members which are yet to be prepared or envisioned. This further evidences that the specific examples set forth in the instant specification do not constitute support for the claimed genus or a substantial portion thereof.

Response to Arguments

8. Applicant’s arguments filed December 22, 2003 have been fully considered but are not found persuasive. The examiner’s rationale is set forth below.

9. Applicant refers to the specification at pages 8 and 9 and states that the instant specification contains an adequate description of a “so-called intelligent material”. While the terminology is indeed referred to in the cited portion of the specification, it is not deemed to be adequately described. The cited portions of the specification merely exemplifies what a “so-called intelligent material” *could* be. As stated in the rejection, a description of a compound in terms of its function fails to distinguish the compound from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. Instant claim 31 includes certain functional requirements on the “so-called intelligent material”; however the description is not adequate for this material.

10. Note that an objective standard for determining compliance with the written description requirement is, “does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). The examiner maintains that the above standard is not met. Thus, for these reasons and the reasons of record, the above rejection under the first paragraph of 35 U.S.C. 112 is maintained.

Claim Rejections - 35 USC § 112

11. Note that some minor changes to the rejections below are made in light of applicant’s arguments and/or to improve clarity.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-7, 9, 10, 17-19, 24-36 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are very confusing in general and the following applies to all claims: MPEP 2173.02: If the scope of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of certainty, a rejection of the claims under 35 U.S.C. 112, second paragraph is appropriate. *In re Wiggins*, 488 F.2d 538, 179 USPQ 421 (CCPA 1973).

This is especially true when one considers the election of species requirement in the instant case. The examiner asked repeatedly for clarification with respect to the instant claims and the elected species of solid support. Currently the elected species of solid support is film or tape. This is still deemed to be confusing with respect to certain dependent claims and how they read on the elected species. Rejections specific to each claim are set forth below.

A. With respect to the elected species of solid support is film or tape, claims 27, 28 and 41 are confusing because it is unclear how the "film or tape" can be placed in individually identifiable containers or different compartments.

B. Claim 6 is confusing because it is completely unclear how the material "allows for spontaneous release of the analytes". This is relative terminology which renders the claim indefinite. The terminology is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and

one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claim 7 is indefinite for the same reasons pertaining to “controlled release of the analytes”.

C. Claims 17-19 are confusing because it is unclear how the elected support of “film or tape” is coated with a membrane, monolayer or film (claim 17) or is an information carrier (claim 18) or is reflective (claim 19).

D. With respect to the elected species of solid support is film or tape, claim 25 is confusing because it is unclear how each analyte can be applied to a single “film or tape” and claim 26 is confusing because it is unclear how the single “film or tape” can be rod or spherical shaped.

E. Claim 31 refers to a “so-called intelligent material”. This is completely indefinite as it is wholly unclear what is being referred to and thus the metes and bounds of the claim cannot be determined.

F. Claim 1 (and all claims dependent thereon) recites a method for the rapid screening of analytes. The term “rapid” is relative terminology which renders the claim indefinite. The terminology is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Response to Arguments

14. Applicant’s arguments filed December 22, 2003 have been fully considered but are not found persuasive. The examiner’s rationale is set forth below.

15. With respect to rejection A, the rejection is now directed only to claims 27, 28 and 41. These claims do require individually identifiable containers or different compartments. Applicant has not addressed the indefiniteness of these claims and the nature of a film or tape seems to preclude their use in individually identifiable containers or different compartments.

16. With respect to rejection B, applicant argues that the terminology “allows for spontaneous release of the analytes” and “controlled release of the analytes” is not indefinite. Applicant states that such is “known to those of ordinary skill in the art” and also points to the instant specification for “characterization and examples of such terms”. What applicant points to in the specification is a very limited explanation of the terminology. Most importantly, the specification does **not** provide a standard for ascertaining the requisite degree for this relative terminology.

17. With respect to rejection C, the examiner maintains that it is unclear how the elected support of “film or tape” is coated with a membrane, monolayer or film (claim 17) or is an information carrier (claim 18) or is reflective (claim 19). Applicant argues that this terminology is common and understandable to one of ordinary skill. The examiner respectfully disagrees. It appears that the claim is incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The incomplete nature of the claims renders them indefinite.

18. With respect to rejection D, the examiner maintains that it is unclear how each analyte can be applied to a single “film or tape” (claim 25) and how the single “film or tape” can be rod or spherical shaped (claim 26). Applicant argues that this terminology is common and understandable to one of ordinary skill. The examiner respectfully disagrees. The examiner’s position is that the relationship of elements is unclear (again see MPEP § 2172.01). The nature of a film or tape seems to preclude the use as “single solid supports”. Are there multiple films or tapes, one for each analyte? With respect to claim 26, Applicant argues that a film or tape could exist in a spherical or rod form (one example, a soap bubble). While this may be true, it is not at all relevant to the instant claims (are the solid supports soap bubbles?).

19. With respect to rejection E, the examiner maintains that “so-called intelligent material” is indefinite. The portions of the specification pointed to by applicant are simply not adequate to define this terminology (at best it gives limited examples of such).

20. With respect to rejection F, it appears that applicant is arguing that the term “rapid” is not to be given any patentable weight as it appears in the preamble and none of the method steps. If so, then the examiner’s position is that the term should be removed from the claims to avoid any confusion in claim interpretation.

Claim Rejections - 35 USC § 102

21. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

22. Claims 1, 5, 6, 7, 9, 10, 17, 24-26, 29, 30 and 32-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Lerner et al (US 5,601,992).

Lerner et al discloses a method that reads on that of the instant claims.

Specifically, the reference discloses detecting the interaction between an oligomeric molecule (reading on claimed analyte) and a target (see, e.g. Abstract). In the method of Lerner et al, a plurality of beads containing peptide analytes are applied to a substrate surface and allowed to diffuse therein (see, e.g. column 21, lines 33-66 – “[t]he oligomeric molecules diffuse through the substrate and interact with a target”). This reads on the claimed step b) of releasing the analytes from the solid supports. The reference also reads on step a) of having analytes on at least one solid support in an isolated fashion, see, for example, column 3, lines 5-22). Beads as solid supports are used for the peptide analytes and the interaction tests were run in culture dishes (see, e.g. Examples 1 & 3 of the reference), this reads on the supports recited in the instant claims. The culture dishes of the reference have gels thereon, see, for example, column 29, lines 62-66. This reads on a coated solid support as recited in the instant claims. The peptide analytes and their preparations (see, e.g. Example 1) read on the analytes recited in instant claims 29, 30 and 32. Various cellular targets are also described by the reference (see Example 2 and column 21, line 66 – column 22, line 67)

reading on claim 33. In the reference, pigment dispersion is measured (see, e.g. column 25, line 55 – column 26, line 52); this reads on the limitations of instant claim 36.


Status of Claims/Conclusion

23. No claims are allowed.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (571) 272-0805. The examiner is on an increased flextime schedule; the best time to contact the examiner is Monday-Friday from 6:00-10:00 a.m.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Maurie Garcia Baker, Ph.D.
March 21, 2004



MAURIE GARCIA BAKER PH.D
PRIMARY EXAMINER